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| APPLICATION NO.                                                                              | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|----------------------------------------------------------------------------------------------|-------------|----------------------|-----------------------|------------------|
| 10/018,470                                                                                   | 11/21/2002  | Claire Marie Fraser  | CHIR-0319             | 2853             |
| 7590                                                                                         | 01/22/2009  |                      | EXAMINER              |                  |
| Chiron Corporation<br>Intellectual Property R440<br>PO Box 8097<br>Emeryville, CA 94662-8097 |             |                      | NEGIN, RUSSELL, SCOTT |                  |
|                                                                                              |             |                      | ART UNIT              | PAPER NUMBER     |
|                                                                                              |             |                      | 1631                  |                  |
|                                                                                              |             |                      | MAIL DATE             | DELIVERY MODE    |
|                                                                                              |             |                      | 01/22/2009            | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |
|------------------------------|--------------------------------------|--------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/018,470 | <b>Applicant(s)</b><br>FRASER ET AL. |
|                              | <b>Examiner</b><br>RUSSELL S. NEGIN  | <b>Art Unit</b><br>1631              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 October 2008.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4, 25, 26 and 83-85 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 25 and 26 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1, 2 and 83-85 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 October 2008 has been entered.

Claims 3-4 and 25-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 June 2005.

Claims 1-4, 25-26 and 83-85 are pending in this application, and claims 1-2 and 83-85 are examined in this Office action.

***Withdrawn Objections/Rejections***

The objection to claim 1 is withdrawn in view of amendments filed to the instant claims on 27 October 2008.

The rejections of claims 1 and 2 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter are withdrawn in view of amendments filed to the instant set of claims on 27 October 2008.

The rejections of claims 1-2 under 35 U.S.C. 103(a) as being unpatentable over Ribot et al. are withdrawn in view of amendments to the instant set of claims filed on 27 October 2008.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**The following rejection is NEWLY applied and necessitated by amendment:**

Claim 85 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim 85 recites that the putative open reading frame does NOT consist of one or more of NMB0427, NMB0428, NMB0429, and NMB0430. While page 5 of the original specification discloses that Appendix B of the specification teaches all of the NMB open reading frames of the sequence, no Appendix B has been filed in the instant application, nor are there any other papers disclosing the ORFs designated by the NMB numbers. While original, withdrawn, claims 8, 9, 12, and 14 each recite the term "NMB open reading frames," these original claims are not specific as to any particular NMB reading frames (e.g. those recited in instant new claim 85). The drawings as originally

filed do not disclose any reading frames designated as "NMB open reading frames." While applicant reiterated the listing of the sequence in question with ORFs annotated as part of the amendment filed on 27 October 2008, this annotation was not made at the time of filing, and, even if it were, it is not designated as to which NMB ORF corresponds to each ORF annotated in the sequence listing. Thus, since the NMB ORFs are not disclosed or referenced in the prior art, the negative limitations which exclude these respective ORFs are considered NEW MATTER. Consequently, claim 85 is considered to recite limitations with NEW MATTER.

***Claim Rejections - 35 USC § 103***

The following rejection is NEWLY applied:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 83-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribot et al. [WIPO WO 98/17805; published 30 April 1998] in view of Chee et al. [US Patent 5,795,716; issued 18 August 1998; filed 21 October 1994]

The claims are drawn to a method for identifying an amino acid sequence from the *N. meningitidis* serogroup B strain MC58 genome, comprising the steps of:

- providing a computer database comprising the *N. meningitidis* serogroup B strain MC58 genome sequence of SEQ ID NO:1;
- searching for putative open reading frames or protein-coding sequence within the computer database;
- identifying an amino acid sequence corresponding to the searched putative open reading frame or protein coding sequences; and
- outputting the identified amino acid sequence to a user display or storing the identified amino acid sequence to a computer readable media.

Claim 2 further comprises searching the computer database containing SEQ ID NO:1 for an initiation codon; and searching for an in-frame termination codon downstream of the initiation codon.

Claim 83 is further limiting comprising outputting the identified amino acid sequence to a user display.

Claim 84 is further limiting comprising storing the identified amino acid sequence to a computer storage medium.

Claim 85 is further limiting wherein the putative open reading frame does not consist of one or more of NMB0427, NMB 0428, NMB0429, and NMB0430.

Ribot et al. disclose a method of automated DNA sequence analysis of PCR fragments using a dye terminator reaction method (page 57, lines 2-7) for identifying serogroup B amino acid sequences comprising the step of computer assisted analysis (page 57, lines 5-7) for putative open reading frames (see Figure 1 of Ribot et al. and SEQ ID NO 6 and SEQ ID NO 3 of Ribot et al.) or coding an amino acid sequence with *N. meningitidis* nucleotide sequence (SEQ ID NO: 1 of Ribot et al.). As shown in Ribot et al., SEQ ID NO: 1 of Ribot et al. comprises the initiation codon (i.e. ATG, see SEQ ID NO:1 of Ribot et al., line 1, positions 16-18), an in frame termination codon (see SEQ ID NO:1 of Ribot et al., line 1, position 1100, and 1148). Ribot et al. discloses a method for searching ORFs or protein coding sequences of *Neisseria meningitidis* (Ribot et al., pages 57-59 expands on this analysis). Additionally, Figures 5-7 of Ribot et al. comprise a database of several SEQ ID NOs: discussed on page 6, lines 20-30 of Ribot et al. with protein (i.e. amino acid) sequences assigned to the ORF.

However, Ribot et al. does not discuss analysis of the entire instant SEQ ID NO. 1 from *N. meningitidis*. Additionally, Ribot et al. does not discuss the computer storage medium or user display as recited in the instantly rejected claims.

The computer method and its method of use of identifying and analyzing sequences of biomolecules (i.e. SEQ ID NO 1 of the instant application) as stated in the

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instant set of claims differs from the claimed invention only in the content of the sequence used in the search. The MPEP states in 2106.01:

When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See Gulack, 703 F.2d at 1384, 217 USPQ at 403; see also Diehr, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

The above paragraph cites four court decisions which, when taken together, give the same message and theme regarding prior art and patentability of computerized media

The difference between Ribot et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the method functions, i.e., the database of the claimed computer method does not alter the computer method to perform a different function than the computer system of Ribot et al. Therefore, the sequence information of the instant claims do not patentably distinguish the claim from the prior art.

The patent of Chee et al. discussed the computer-aided visualization and analysis system for sequence evaluation. Specifically, the system as illustrated in Figure 1 has a computer storage medium and a display device.

It would have been obvious to someone of ordinary skill in the art at the time of the instant invention to modify the sequence database of Ribot et al. by use of the

storage and visualization systems of Chee et al. wherein the motivation would have been that the storage and visualization of Chee et al. have the advantage of more conveniently viewing and recording data pertaining to computer visualization of sequences [i.e. see Figure 1 of Chee et al.]

Response to Arguments:

Applicant's arguments filed 26 March 2008 have been fully considered but they are not persuasive.

In response to arguments regarding the MPEP pertaining to nonfunctional descriptive material, it is maintained that Ribot et al. teaches all the claimed method steps (except for the display and storage media steps- which are taught in Chee et al.). As explained above, since the sequence in the instant set of claims is non-functional descriptive material, it does not patentably distinguishable the claims from prior art that teaches all of the embodiments of the claim except this non-functional descriptive material. Consequently, while applicant argues that there are differences between the sequences of Ribot et al. and the instantly claimed sequences, these differences amount to differences between non-functional descriptive materials.

Applicant continues to argue that the sequence itself is scientifically useful and therefore is functional on pages 6-7 of the Remarks. This argument is not persuasive because the rejection is not one under 35 U.S.C. 101 regarding utility, but is one of obviousness under 35 U.S.C. 103. While it is not disputed that the instantly rejected claims have utility, the issue at hand is whether there is a functional relationship

between that computer and the sequence files comprised within a database inserted into the computer. For the reasons discussed above, there is no such relationship. Additionally, the sequence is given patentable weight (note that otherwise the rejection would be made under 35 U.S.C. 102); however, the sequence does not patentably distinguish the claimed method from Ribot et al. because, as described above, the steps taught by Ribot are the same as those claimed, wherein the sequences in the database to be searched do not alter the steps, thus the sequence claimed is nonfunctional descriptive material.

Applicant is advised that a possible solution to overcoming this rejection is to incorporate withdrawn claim 3 into instant claim 1 wherein the physical expression of proteins from the actual sequence (i.e. not just an *in silico* representation of SEQ ID NO 1) is required. Alternatively, or in addition, applicant may reiterate the *in silico* database limitations and at the end of the claim add a verification step between the computer and empirical method steps to observe whether the *in silico* method has succeeded. The above are suggestions for limitations to overcome the instant rejection and are NOT suggestions for specific claim language/amendments. Applicant is reminded that any amendment must be fully supported and enabled by the originally filed disclosure.

### ***Conclusion***

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the

central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)).  
The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.  
For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/  
Russell S. Negin  
16 January 2009

/Marjorie Moran/  
Supervisory Patent Examiner, Art Unit 1631